From:	General Board of Pharmacy Subscriber List on behalf of Board of Pharmacy
To:	PHARM-GENERAL@DCALISTS.CA.GOV
Subject:	Morphine Sulfate 0.5 mg/mL Preservative Free in 0.9 percent Sodium Chloride by Pharmakon Pharmaceuticals: Recall - Super-potent Product
Date:	Thursday, February 18, 2016 9:47:56 AM

AUDIENCE: Pharmacy, Nursing

ISSUE: FDA is alerting health care professionals of a voluntary recall of morphine sulfate 0.5 mg/mL preservative free in 0.9% sodium chloride, 1 mL syringe, CII, for intravenous use made and distributed by Pharmakon Pharmaceuticals, in Noblesville, Indiana, because the product is super-potent. Pharmakon initiated the voluntary recall on February 11, 2016, after receiving laboratory results showing the product was super-potent. On February 16, 2016, FDA was alerted of serious adverse events in three infants associated with the use of the recalled morphine sulfate products from Pharmakon.

Injecting a patient with super-potent morphine could result in serious consequences including respiratory depression, coma, and death.

BACKGROUND: The recalled product was made on February 3, 2016, with an expiration date of March 19, 2016, and labeled with lot E52418EV11C and NDC 45183-0322-78. The recalled product was distributed to two medical facilities – one in Indiana and one in Illinois.

RECOMMENDATION: Health care professionals should immediately check their medical supplies, and quarantine the recalled product from Pharmakon.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report
- Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

[02/16/2016 - Alert - FDA]

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